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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/337,756	06/22/1999	HANS J. HANSEN	018733/0884	9359

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FOLEY & LARDNER
3000 K STREET NW SUITE 500
P O BOX 25696
WASHINGTON, DC 20007

EXAMINER

SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

337,156

Applicant(s)

HANSEN et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 7/20/01
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 12-20, 30, 51-52 is/are pending in the application.
- ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 12-20, 30 is/are rejected.
- ☒ Claim(s) 51-52 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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The amendment of 7/19/01 (Paper 13) has been entered. Claims pending and under examination are 1, 12-20, 30 and 51-52.

The provisional 101 and 103 obviousness type double patenting rejections of record have been withdrawn, due to cancellation of the conflicting claims in the instant and copending applications.

The 112, second paragraph rejections of record have been withdrawn, due to applicant's amendment and urgings. New 112, first and second paragraph rejections are stated herein below, as they pertain to the amended claims.

Claims 1, 12-20 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

2012/31/02
Claims 1 and ³⁰~~50~~ each fail to set forth any functional relationship between the conjugated enzyme and the conjugated prodrug.

Claim 20 is unclear by reciting a "detectable radionuclide", since base claim 1 refers to "treating" rather than "detecting". Claim 20 fails to set forth any functional relationship of the radionuclide to the method of claim 1.

Claims 1, 12-20 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims contain new matter.

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Specifically independent claims 1 and 30 each recite, in part D), "a second targetable conjugate which comprises a carrier portion and a prodrug", without also reciting the limitation that the enzyme is capable of converting said drug to a prodrug at the target site, as was recited in original claims 1 and 30, part D) 4) of each. In other words, the limitations of new claim 51 would be required in amended claims 1 and 30, because the examiner can find no embodiment described without this limitation. Alternatively, applicant could insert the limitation of new claim 52 (supported by original claim 1, part D) 3) in conjunction with dependent claim 2) into amended claims 1 and 30.

End
12/31/02

Claim 20 contains new matter because the examiner cannot find where the original disclosure specifically disclosed the use of a detectable radionuclide on the bispecific antibody, in conjunction with the recited first (enzyme) and second (prodrug) conjugates.

Claim 20 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

Applicant's disclosure has not set forth the purpose for or utility of providing the recited detectable radionuclide on the bispecific antibody.

Claim 20 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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Claims 1, 12-20 and 30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use/provision of a prodrug having the limitations recited in claim 51 or 52, does not reasonably provide enablement for the use/provision of a prodrug which bears no functional relationship to the enzyme. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant's disclosure has given no direction as to how to use a prodrug which would not bear any functional relationship to the enzyme, as recited in claims 51 or 52, nor would one of skill know how to obtain any operative prodrug which fails to have such a relationship to the enzyme.

Applicant's amendment has overcome the prior art rejections of record in Paper 10.

The amendment has also overcome the provisional obviousness rejection over copending application 09/205,243.

The pending claims are allowable over the prior art of record.

> Hansen (5,851,527) is cited as of interest for disclosing prodrugs and other kinds of drugs conjugated to a substrate or polymeric carrier. Hansen also discloses use of bispecific antibodies for targeting. He, however, does not disclose a bispecific antibody having specificities for a target antigen and for an epitope on a carrier portion of a carrier enzyme conjugate. Also, he does not disclose a carrier prodrug conjugate which has a an epitope on the carrier portion.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

July 24, 2002

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182-1644